March 2, 2021

Appeal No.: 18-0097AA
FDA Case No: 2018-6729

Aidan Hunt
3010 Amidon Drive
Greensboro, NC 27410

Dear Mr. Hunt:

This responds to your correspondence received September 4, 2018, appealing the response by the Food and Drug Administration (FDA) to your August 17, 2018, Freedom of Information Act (FOIA) request for records relating to the inspection of Meridian Medical Technologies (MMT) referenced in the Warning letter posted at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm574981.htm.

FDA assigned your request to the Office of Regulatory Affairs (ORA) for processing. On August 28, 2018, FDA provided inspection records, 483 responses and Warning Letter responses, which were partially redacted under Exemption 4 as confidential commercial/trade secret information. On the same day, your request for the establishment inspection report (EIR) was denied under Exemption 7(A).

In your appeal, you state that some or all of the information redacted should not be withheld under Exemption 4, and also that FDA had not adequately identified the reasons some of the information was redacted. You also state that disclosure of the EIR is not reasonably likely to interfere with enforcement proceedings and therefore should not be withheld under Exemption 7(A). [1]

After careful consideration of your appeal, we have concluded that the FDA correctly decided to withhold information responsive to your request under Exemptions 4 and 7(A) and the FDA's implementing regulations. Set forth below is an explanation for our appeal determination.

Exemption 7(A)

Exemption 7(A) authorizes the withholding of "records or information compiled for law enforcement purposes, but only to the extent that production of such law enforcement records or information…could reasonably be expected to interfere with enforcement proceedings."

Courts have held the exemption is available, for example, where the disclosure of internal investigational documents could reveal the potential scope and direction of an ongoing investigation, or

[1] FDA called you and explained the EIR is open until the investigation is closed; further regulatory action against the firm can occur until the investigation closes.

provide premature insight into the Agency's factual knowledge and internal deliberation.[2] Public knowledge of such matters could impede the agency's ability to take appropriate enforcement actions. In your appeal, you state that the FDA has publicly disclosed a redacted version of the Form FDA 483 and a warning letter. However, these documents were prepared for disclosure to MMT and, upon request, to other members of the public. In contrast, an EIR is an internal memorandum in the investigational file, which may contain personal conclusions and recommendations and additional information, which generally is not disclosed outside the agency before a matter is closed except to other authorized government officials. Public disclosure of such internal memoranda before a matter is closed could interfere with the investigation, and in this case, I conclude that the EIR was properly withheld under Exemption 7(A).

Exemption 4

Exemption 4 of the FOIA protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential."[3] Additionally, the FDA's regulation at 21 C.F.R. 20.61(c) generally prohibits the disclosure by the FDA of "[d]ata and information submitted or divulged to the [FDA] which fall within the definitions of a trade secret or confidential commercial or financial information." In order to withhold information under Exemption 4, it is necessary to establish that the information is either (1) a trade secret or (2) that it is a) commercial or financial, b) obtained from a person, and c) privileged or confidential.[4]

Trade Secret

Some of the information that was redacted from the records responsive to your request has been properly withheld by the FDA because it qualified as trade secret information under the FOIA, the FD&C Act, and FDA's implementing regulations.

For the purposes of FOIA, a "trade secret" is defined as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort."[5] The definition also incorporates a requirement that there be a "direct relationship" between the trade secret and the productive process.[6] FDA's regulation at 21 C.F.R. § 20.61(a) defines a "trade secret" in the same way.

Courts have long recognized as trade secrets information that describes confidential elements of product design and the manufacturing process, including product specifications and the processes and methods used as quality controls.[7] HHS' regulations at 45 C.F.R. § 5.65, as well as sections 301(j) and

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[2] *Citizens for Responsibility & Ethics in Wash. v. United States DOJ*, 870 F. Supp. 2d 70 (D.D.C. 2012)

[3] 5 U.S.C. § 552(b)(4).

[4] *See Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1290 (D.C.Cir. 1983); *Herrick v. Garvey*, 200 F. Supp. 2d 1321, 1324 (D. Wyo. 2000), *aff'd*, 298 F.3d 1184, 1193-95 (10th Cir. 2002).

[5] *Pub. Citizen*, 704 F.2d at 1288; *see also Freeman v. Bureau of Land Mgmt.*, 526 F. Supp. 2d 1178, 1188 (D. Or. 2007); *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 93 F. Supp. 2d 1, 8 (D.D.C. 2000); *Anderson v. HHS*, 907 F.2d 936, 944 (10th Cir. 1990).

[6] *Pub. Citizen*, 704 F.2d at 1288; *accord Ctr. for Auto Safety v, Nat'l Highway Traffic Safety Admin.*, 244 F.3d 150-51 (D.C. Cir. 2001).

[7] *See*, *e.g.*, *Heeney v. FDA, No. 97-5461, slip op. at 7. 12-13 & n.13 (C.D. Cal. Mar. 18, 1999)*, No. 97-5461, slip op. at 12-13 & n.13 (C.D. Cal. Mar. 18, 1999) ("Design and testing data, including specification of the materials used in constructing the

520(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 331(j) and 21 U.S.C. 360j(c)), also prohibit disclosure in response to a FOIA request of trade secret information and/or confidential commercial information that the FDA obtains under section 704 of the Act (which authorizes inspections of establishments that manufacture drugs and medical devices.

Some of the information responsive to your request was properly withheld because it includes trade secret information. Specifically, FDA properly withheld portions of records that reflect confidential details of the firm's processes, product design, and specific quality control methods because that information constituted trade secret. Although you state in your appeal that certain information that was withheld is not confidential or is publicly available, this is information that manufacturers customarily keep confidential and we have not found this information in the public domain. We respond further to some of your specific assertions below.

Commercial or Financial Information

As previously mentioned, information falls within Exemption 4 if it is (a) commercial or financial, (b) obtained from a person, and (c) privileged or confidential.[8]

For the purposes of Exemption 4, the terms 'commercial' and 'financial' are given their ordinary meanings and information is considered commercial if the party from whom the information is obtained has a commercial interest in the information.[9] Here, the information that was withheld in response to your request consisted of information pertaining to the manufacture of a commercially marketed drug product. This information was clearly commercial in nature.

The information that was withheld in response to your request under Exemption 4 had also been "obtained from a person." The term "person" refers to individuals as well as to a wide range of entities, including corporations.[10] The withheld information was obtained from Meridian Medical Technology, Inc., a corporation, which is considered a "person" within the scope of Exemption 4.

The question then is whether the information is considered to be privileged or confidential. In your appeal, you contend that much of the redacted information is not protected as confidential commercial information because its release could not cause substantial competitive harm to MMT or others. However, in *Food Mktg. Inst. v. Argus Leader*, 139 S. Ct. 2356 (2019), the Supreme Court clarified that agencies are not to apply the substantial competitive harm standard of *National Parks & Conservation Association v. Morton*, 498 F.2d 765 (D.C. Cir. 1974) to decide whether requested information is exempt from disclosure under FOIA Exemption 4. Rather, the Supreme Court explained that commercial or financial information obtained from a person is considered "confidential" for purposes of Exemption 4 at least if it is (1) both actually and customarily treated as private by its owner and (2) provided to the

product…"; "substantial investment that companies … make in developing protocols and methodologies for design, testing, and production"); *Citizens Comm'n on Human Rights v. FDA*, No. 92-5313, 1993 WL 1610471, at *7 (C.D. Cal. May 10, 1993) ("information about how a pioneer drug product is formulated, chemically composed, manufactured, and quality controlled"), aff'd in part & remanded in part on other grounds, 45 F.3d 1325 (9th Cir. 1995);

[8] *See* 5 U.S.C. § 552(b)(4); *Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1290 (D.C.Cir. 1983); *Herrick v. Garvey*, 200 F. Supp. 2d 1321, 1324 (D. Wyo. 2000), *aff'd*, 298 F.3d 1184, 1193-95 (10th Cir. 2002).

[9] *Pub. Citizen*, 704 F.2d at 1290.

[10] 5 U.S.C. 551 "For the purposes of this subchapter - … (2) "person includes an individual, partnership, corporation, association, or public or private organization other than an agency; …"; *See e.g. Comstock Int'l v. Export-Import Bank*, 464 F. Supp. 804, 806 (D.C. Cir., 1979).

government under an assurance of privacy.[11] We apply this standard to your appeal, and therefore do not address whether disclosure could cause substantial competitive harm to ascertain whether information falls under Exemption 4.

The information at issue in this appeal includes trade secrets relating to the manufacturing process, such as confidential product specifications and quality control procedures, the identity and terms of contracts with certain suppliers, and internal product trace-back information. This information was properly considered confidential commercial information. It is information of a type that firms customarily maintain in confidence and which FDA has indicated it does not disclose, and we have not found this information in the public domain.[12]

Below we provide further responses with respect to certain information you reference in your appeal.

483 Redactions

You state that information redacted in Observation 1, paragraph A, p. 1 is an estimate of potential failures caused by a third-party component deformity and should not have been redacted because it is not trade secret or confidential commercial information. The powerpak assembly lot numbers were properly redacted as confidential commercial information; such information is not customarily released by firms and we did not find this information in the public domain, including in connection with the recall. FDA's practice has been to protect confidential internal tracing information, which was not released in the recall you refer to or necessary to effectuate the recall.[13]

With respect to Observation 3, paragraph B, the redactions you reference were to protect descriptions of confidential policies and testing procedures used for quality control. You state that this information is not confidential because all combination device manufacturers must maintain such a policy and would be subject to the same guidance from the FDA. However, while FDA issues general guidance, it does not specify what type of testing must be conducted. The information redacted in this section was not found publicly and is considered commercial confidential and trade secret.

With respect to Observation 6, p. 7, you state that the redacted language after the words "EpiPen Jr., and" reflects the name of an approved product that is approved and already known to the public. This assumption is incorrect; the information under the redaction is confidential and was properly withheld as confidential commercial information.

Observation 6, and 6-9 pp. 7-11, you claim that none of these redactions is trade secret or commercial confidential. You state that the specifications which a certain product is committed to meet are only tangentially related to the productive process, and the redacted information is not CCI because it would not substantially aid competition and because there is not actual competition relevant to the production of the EpiPen NGA auto-injector. We have responded above to similar assertions you have made with respect to other redactions in the Form FDA 483. The redacted information relates to the firm's

[11] *Argus Leader*, 139 S. Ct. at 2366.

[12] See Section 301(j) of the FD&C Act (generally prohibiting disclosure of trade secret information obtained under section 704); 21 C.F.R. 61(b) (defining "confidential commercial information"); "What is Confidential Commercial Information", available at https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/communications-outreach/information-sharing#IS2 (last visited February 16, 2021).

[13] "What is Confidential Commercial Information", available at https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/communications-outreach/information-sharing#IS2 (last visited February 16, 2021).

confidential test limits and specific test methods, and is considered commercial confidential information and trade secret information.

Warning Letter response redactions

You state that pages 30-31 were withheld in full and the information is not trade secret. Pages 30-31 were released with redactions and not withheld in full. The redactions are process and testing specifications which are confidential commercial information.

Tables under the heading "Quality Agreements," (pages 34-35) you state that there is no competition and thus no competitive harm to MMT by releasing these terms. These confidential agreements between MMT and its contract manufacturer meet the criteria for commercial confidential information outlined above.

You claim the diagram on p. 6 is not trade secret because it could easily be obtained by disassembling the product and is largely contained in patent filings. You further state it is not CCI because no competitors can or do duplicate this patented design. This figure was not found in public documents, is directly related to the manufacturing process, and thus it was redacted as trade secret and commercial confidential.

You ask for the attachments to the warning letter response. FDA FOIA informed you that you did not originally ask for those and you could put in a new request for those attachments. As of today, you have not submitted a new request.

You state in your appeal that the design of the EpiPen is described in the company's patent which can be located on the US Patent and Trademarks Office website. Although the manufacturing design may be listed, the company does not forfeit its right in protecting how the company disseminates or publishes additional information about their product.

In sum, because the information sought by your request that was withheld under exemption (b)(4) of the FOIA (5 U.S.C. § 552(b)(4)) was trade secret and confidential commercial information, the FDA properly withheld the information. The EIR was properly withheld under Exemption 7(A).

This letter constitutes the final decision of the Department in this matter. If you wish, you may seek judicial review in the district court of the United States in the district in which you reside or have your principal place of business, in which the agency records are located, or in the District of Columbia.

Finally, you may seek assistance with the processing of your request from the Office of Government Information Services (OGIS). OGIS serves as the Federal FOIA ombudsman and assists requesters and agencies to prevent and resolve FOIA disputes through mediation. You may contact OGIS in any of the following ways: Telephone: (202) 741-5770; Facsimile: (202) 741-5769; E-mail: ogis@nara.gov; or, via U.S. Mail at:

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Sincerely,

Martina H. Varnado - S

Digitally signed by Martina H. Varnado -S
Date: 2021.03.03 09:24:23 -05'00'

Martina H. Varnado
Director, Office of Executive Secretariat